

Latex Allergy New

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Department of Health and Human Services
Dockets Management Branch (HFD-305)
Food & Drug Administration
5630 Fishers Lane
Rockville MD 20852

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Comments on Federal Register 21 CFR Parts 801, 878, 880 July 30, 1999

My comments pertain to the issue of recommending a maximum limit of glove powder on powdered latex gloves. I am not aware of any medical literature with evidence to suggest that there is a safe threshold for glove powder. I believe the FDA should not make recommendations that sound like "medical recommendations", while in actual fact the recommendations were based on nonmedical considerations, such as industry production, economic and legal considerations. This was evidenced in the rationale written in the Federal Register. As a former health care professional I would state that uninformed health care professional preference is not a reasonable justification for glove powder. Health care professionals have taken a vow to "do no harm" and there is plenty of evidence that powdered latex glove does a great deal of harm. There is no medical evidence that show that 120 mg, or any amount, of powder is safe, especially in regards to latex allergy and a multitude of other adverse health effects caused by glove powder. Please do not provide false reassurances to the consumers by seemingly endorsing a certain powder level.

Labeling the amount of powder in gloves seems reasonable to help the consumer demand drive down the amount powder in gloves. The FDA should leave off the proposed line "FDA recommends no more than 120 mg of powder per glove". The FDA should not legitimize the presence of glove powder. Would the FDA consider a label on cigarettes stating "FDA recommends no more than _____ amount of tar and nicotine per cigarette"? I don't believe that the FDA would lend any legitimacy to "low tar" cigarettes being safe. If the FDA is going to go ahead with the present recommendations then I believe that the label should also include state that NICOTIN recommends only powder free low protein latex gloves. That way the consumer is truly informed and not misleads. Finally I feel that the label should include a line stating "Glove Powder is a hazardous substance and no safe level of glove powder has been established".

Because these are recommendations and not regulations, I would hate to see an action by the FDA to inadvertently appear to lend legitimacy to the presence of a potentially unsafe level of glove powder, and thus, potentially, slow down the progress being made by market forces. I was interested to see the FDA assume that the share for powderfree gloves will increase up to 80% within the next four years (p41718 Fed. Reg.) The recent study done by the ASTM found that the average latex exam glove from the combined sample currently on the market contained 104.3 mg of powder. Certainly the FDA recommendation of a threshold level of 120 mg is set too high, because the status quo is unacceptable.

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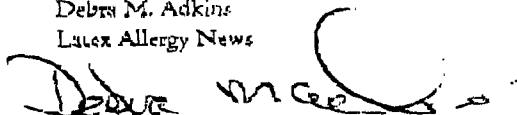
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If market forces alone might reduce the use of powdered gloves to 20% of the market share within 4 years, I would love to see what would happen with a more aggressive leadership role by the FDA and other Governmental agencies. With the magnitude of the health hazard involved there should be regulations, not recommendations. Regulations are long overdue from the FDA, and should be in the best interest of the public health. Potential biased economic and industry production arguments by a small portion of the latex glove industry should not be given more credence than medical research and the health of the public. Since one third of the gloves currently on the market are already powder free, there is significant industry experience operating at a much lower powder level than 120-mg.

In summary: I would like to see requirements, not recommendations, and the phase out of all highly allergic powdered latex gloves in an expeditious fashion. I recommend that the FDA changes the wording on both surgical and exam gloves, and the amount of glove powder in a particular glove be listed. I would also like to the labeling read "Glove Powder is hazardous and no safe level has been established."

Debra M. Adkins
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